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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,761	11/13/2003	Barry E. Boyes	10030532-1	3579

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EXAMINER	
MOSS, KERI A	

ART UNIT	PAPER NUMBER
1743	

MAIL DATE	DELIVERY MODE
06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,761	BOYES ET AL.	
	Examiner	Art Unit	
	Keri A. Moss	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/13/06;11/13/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: The claim 1 preamble should read: "A method to at least determine the binding identity of at least one constituent of a sample, comprising...." Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims **1-36** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by "chromatographic conditions." It is unclear what the scope of this claim limitation is in the context of the invention.

It is unclear what is meant by "binding identity." It is unclear what the scope of this claim limitation is in the context of the invention.

It is unclear what is meant by "pharmaceutical agent." It is unclear what the scope of this claim limitation is in the context of the invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims **1-8, 14-21, 27-36** are rejected under 35 U.S.C. 102(a) as being anticipated by Bailey, Jerome et al (Removing High-Abundance Proteins from Serum, Genetic Engineering News, 1 November 2003, pp.32, 36-37, Vol. 23, No. 19). Bailey discloses a method comprising sequentially contacting a sample with at least a first stationary phase and a second stationary phase under chromatographic conditions, wherein the specificity of said first stationary phase for at least one constituent present in said sample is at least uncertain, and the specificity of said second stationary phase for said at least one constituent is certain, to at least determine the binding identity of said at least one constituent (pgs. 32, 36-37). Bailey also teaches a method of evaluating the specificity of said first stationary phase for said at least one constituent present in said sample. The sample may be contacted with said first stationary phase and then said second stationary phase or vice versa (pgs. 32, 36-37). The method of may further comprise: contacting the sample with the first stationary phase to bind a fraction of said sample that comprises said at least one constituent; separating said binding fraction from said first stationary phase; and contacting said binding fraction with said second stationary phase (pg. 36-37). The first stationary phase comprises a pharmaceutical agent and said method is a method of determining the specificity of said pharmaceutical agent for said at least one constituent present in said sample (p. 37).

The method further comprises analyzing any constituents that did not bind to said second stationary phase (p.37). Analyzing comprises using at least one of: one dimensional gel electrophoresis, two dimensional gel electrophoresis (p. 36) The method may be used a method of determining the specificity of a pharmaceutical agent for at least one constituent present in said sample (p.32). The sample may comprise a population of proteins and said method may be a method of separating a sub-population of proteins from said population of proteins (p. 32 and 36-37) The separating may comprise: contacting said sample comprising a class of proteins with said first stationary phase to bind a fraction of said sample that comprises said population of proteins; collecting said binding fraction from said first stationary phase; and contacting said binding fraction with said second stationary phase so that said sub-population of proteins binds to said second stationary phase and any remaining members of said population do not bind to said second stationary phase (p. 37). The first and second stationary phases comprise ligands chosen from: antibodies or binding fragments thereof, diabodies, minibodies,-antigens, dyes, single chain variants, proteins, glycoproteins, peptides, nucleic acids, vitamins, inorganic chemicals and organic chemicals (Table 2). Said first stationary phases comprises chlorotriazine affinity ligands and said second stationary phase comprises immunoaffinity ligands and are connected by a conduit (p.32). Data representing a result of an analysis step obtained by the method is transmitted to a remote location and received (p.37). 30. Bailey thus discloses a system and a kit comprising the above mentioned stationary phases, a sample and instructions. (p.32 and 36-37).

6. Claims **1,2,6-16,18,20-27,31,33-36** are rejected under 35 U.S.C. 102(a) as being anticipated by Mizushina, YoshiYuki et al. (Flavonoid glycoside: A new inhibitor of eukaryotic DNA polymerase alpha and a new carrier for inhibitor-affinity chromatography, Biochemical and Biophysical Research Communications, vol. 301, no. 2, pgs 480-487 (7 February 2003). Mizushina discloses a method of determining the specificity of a pharmaceutical agent for at least one constituent present in said sample comprising sequentially contacting a sample with at least a first stationary phase and a second stationary phase under chromatographic conditions, wherein the specificity of said first stationary phase for at least one constituent present in said sample is at least uncertain, and the specificity of said second stationary phase for said at least one constituent is certain, to at least determine the binding identity of said at least one constituent (p.481, right column, last paragraph). Said sample is contacted with said second stationary phase first and said first stationary phase second (p.481, right column, last paragraph). The method may further comprise: contacting said sample with said second stationary phase to bind a fraction sample that comprises at least one constituent; separating said non-binding fraction from said second stationary phase; and contacting said non-binding fraction with said first stationary phase (p.481, right column, last paragraph). The first stationary phase comprises a pharmaceutical agent. The method further comprises analyzing any constituents that did not bind to said first stationary phase (paragraph bridging pages 485-486). The analyzing comprises performing immunochemical analysis (paragraph bridging pages 485-486). Yoshiyuki

also teaches that this method may be used to evaluate the specificity of a stationary phase comprising contacting a sample with at least a first stationary phase and second stationary phase under chromatographic conditions, wherein the specificity of said first stationary phase for at least one constituent present in the sample is at least uncertain, and the specificity of said second stationary phase for said at least one constituent is certain (paragraph bridging pages 485-486). The first and second stationary phases comprise ligands chosen from: antibodies or binding fragments thereof, diabodies, minibodies,-antigens, dyes, single chain variants, proteins, glycoproteins, peptides, nucleic acids, vitamins, inorganic chemicals and organic chemicals (p. 481 left column). At least one stationary phase comprises immunoaffinity ligands (p. 481 left column). The first and second stationary phases are connected by a conduit. Yoshiyuki thus teaches a system and a kit comprising the two stationary phases described above and a sample or instructions.

7. Claims **1, 6-8, 14-16, 18, 20, 21, 27-31 and 33-36** are rejected under 35 U.S.C. 102(b) as being anticipated by Jindal et al. (US Pub 2002/0150926). Jindal discloses a method of determining the specificity of a pharmaceutical agent for at least one constituent present in said sample comprising sequentially contacting a sample with at least a first stationary phase and a second stationary phase under chromatographic conditions, wherein the specificity of said first stationary phase for at least one constituent present in said sample is at least uncertain, and the specificity of said second stationary phase for said at least one constituent is certain, to at least

determine the binding identity of said at least one constituent. further comprising analyzing any constituents that did not bind to said second stationary phase (paragraphs 95,101,105 and 109) Said analyzing comprises using liquid chromatography/mass spectroscopy biomolecular interaction (paragraph 209). The method may be a method of determining the specificity of a pharmaceutical agent for at least one constituent present in said sample (paragraph 119). The sample may comprise a population of proteins and said method may be a method of separating a sub-population of proteins from said population of proteins (paragraph 119). The separating may comprise: contacting said sample comprising a class of proteins with said first stationary phase to bind a fraction of said sample that comprises said population of proteins; collecting said binding fraction from said first stationary phase; and contacting said binding fraction with said second stationary phase so that said sub-population of proteins binds to said second stationary phase and any remaining members of said population do not bind to said second stationary phase (paragraph 119). The first and second stationary phases comprise ligands chosen from: antibodies or binding fragments thereof, diabodies, minibodies,-antigens, dyes, single chain variants, proteins, glycoproteins, peptides, nucleic acids, vitamins, inorganic chemicals and organic chemicals (paragraph 105) At least one stationary phase comprises immunoaffinity ligands (paragraph 105). The first and second stationary phases are connected by a conduit (paragraph 109). The method may be one of evaluating the specificity of a stationary phase comprising contacting a sample with at least a first stationary phase and second stationary phase under chromatographic conditions,

wherein the specificity of said first stationary phase for at least one constituent present in the sample is at least uncertain, and the specificity of said second stationary phase for said at least one constituent is certain (paragraph 119) Data is analyzed, forwarded, transmitted to a remote location and received (paragraph 101). Jindal in its entirety teaches a system and a kit comprising the above stationary phases, a sample and instructions (paragraphs 95,101,105, 109 and 119).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keri A. Moss
Examiner
Art Unit 1743

6/25/07

Jill Warden
Supervisory Patent Examiner
Technology Center 1700